3725 2016

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	)
	)
Hans Seiter	) Art Unit: 3728
	)
Appln. No. : 09/423,619	) Ex: T. Arnold, III
	)
Filed : November 15, 1999	)
	)
For : INNER SOLE FOR A SHOE	)

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Klaus Bös, declare as follows:

1) I am the Director of the Institute for Sports and Sports Science in Karlsruhe, Germany. I received a degree in Mathematics and Sports from the University of Heidelberg, Germany and my Doctorate in the Dimensions of Motor Activity in 1980. I have done post - doctoral work in the field of Diagnosis of Motor Capabilities. From 1985 - 1987, I was a professor at the University of Frankfurt, Germany. In 1985 I was also the head of the Institute for Sorts and Sports Science at the University of Regensburg, Germany. From 1995 to 1998 I was again a professor at the University of Frankfurt, Germany, and from 1999 to the present, I am the head of the Institute for Sports and Sports Science at the University of Karlsruhe, Germany

2) I am familiar with the inner sole which forms an embodiment of the invention disclosed in the application noted above, which inner sole has been identified by Dr. Hans Seiter

as the "VenoPed."

3) I am familiar with the clinical studies conducted by Dr. Hans Seiter on both men and women using the VenoPed inner sole to improve venous flow of blood in the human foot.

4) I, along with Dr. Hans Seiter, gave a talk at the World Congress of the International Union of Phlebology regarding the beneficial effects of the VenoPed. A summary of our conclusions is found in the Enclosure attached hereto.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 19.1.2004

Klaus Bös

14.WORLD CONGRESS OF THE UNION INTERNATIONALE DE PHLEBOLOGIE

INFLUENCE OF SEVERAL FOOT-MUSCLE PUMP SUPPORTING DEVICES ON THE VENOUS FLOW VELOCITY DURING A SCHEDULED WALKING PROGRAM

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Key words: venous flow rate, foot muscle pump, venous shoe insole, compression stocking, walking

The main principle in the treatment of the chronic venous insufficency is the augmentation of the venous flow velocity to reduce and/or prevent the well known problems resulting from the hypertonus of the peripherial veins. Walking which stimulates the foot muscle pump is the ideal sports activity for the veins. The sole of the foot consists of a tight and fine mesh-like network of veins which drain into the deep venous system and into the saphena magna and parva.During walking this foot muscle pump is squeezing this sponge-like network of these foot-sole veins and it comes to an acceleration of the venous flow velocity in the leg. We investigated the influence of a new muscle pump supporting device (shoe insole) on the venous flow rate in comparison with medical stockings of different categories(I,II)during a defined walking schedule with normal volunteers (Vena femor.superfic., Duplex technique, Woodway running-board).In the comparison without any supporting agent we found an acceleration of the venous flow velocity with this new developped shoe insole of 25-30%, with a compression stocking (I) of 20% and with a compression stocking (II) of 30%.
We conclude that this new shoe insole is an effective device to increase the venous flow velocity.

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DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Hans Seiter declare as follows:

1) I am the inventor of the invention disclosed and claimed in the above-noted application.

2) The inner sole which forms an embodiment of the noted invention has been identified by me as the "VenoPed."

3) I am a vascular/orthopedic surgeon having received my MD degree in 1980 from the University of Tuebingen, Germany. Until 1992, I was an Assistant Professor in the Department of Thoracic and Cariovascular Surgery at the University of Tuebingen, Germany. In 1995, I established the SEITER-KLINIK, which is one of the five largest clinics in Germany specializing in Phlebology. I am also the Author of the book "Successful Treatment of Venous Disorders" published in 1999 by Moderne Industrie, 86895 Landsberg/Tech, Germany.

4) I am the author of Enclosure A attached hereto and titled: VenoPed - The Shoe Insole for the Improvement of the Venous Reflux. On page 4 of this Enclosure, the Results reported show that there was a 35% to 38% increase in the velocity of the venous reflux because of the use of the VenoPed. The clinical study data clearly supports this conclusion for both men and women.

5) I, along with Dr. Klaus Bös, the Director of the Institute for Sports and Sports Science gave a talk at the World Congress of the International Union of Phlebology regarding the beneficial effects of the VenoPed. A summary of our conclusions is found in Enclosure B attached hereto.

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

Date 15.11.04

Hans Seiter

ENCLOSURE A

VenoPed – The shoe insole for the improvement of the venous reflux

Vein complaints, especially the varicose veins, are a national disease. 65% of all adults in Germany and in other industrial countries have morbid changes in their veins. Already amongst juveniles between the ages of 14 – 16 years is the venous system no longer healthy. Approximately 1.5 million people in Germany have an open leg. Due to vein diseases, the national economy loses yearly 13.000 working years. 7 billion DM is given out yearly by the health insurance companies for the treatment of vein diseases.

Varicose veins are usually traced back to a congenital, inherited weakness of the connective tissue. The consequences of the varicose vein disease when it is not timely treated are phlebitis, thrombosis, pulmonary embolism, swollen and open legs.

Varicose veins is a chronic disease which dynamically progresses over the years when untreated.

The above mentioned weakness of the connective tissue results to a weakening of the walls of the veins in the venous system of the leg. This leads to an incomplete closure of the valves of the veins thereby causing the blood in the veins to sink back into the leg since it is unable to flow completely upwards as it usually does - from the foot through the leg into the body. The peripheral venous pressure increases giving rise to congestion complaints, swollen legs, skin disorders and varicose veins which evolves into open legs when not treated on time.

Vein complaints can be significantly treated by accelerating the flow velocity of the upwards bound venous blood in the body.

The venous reflux can be increased through special gymnastics and the wearing of surgical stockings.

A rapid expulsion of the venous blood out of the stretched network of venous vessels of the foot is very important for the increment of the venous reflux. The vein gymnastics and the surgical stockings in this case contribute insufficiently.

The anatomy:

The vascular sole:

The sole of the foot consists of a tight and fine mesh-like network of superficial veins. These drain through the medial and fibula marginal vein into the saphena magna and saphena parva.

In the foremost region of the foot, these veins are connected through the subcutaneous venous plantar arch. The venous plantar arch drains into the dorsal plantar arch.

The deep veins of the foot (medial and lateral plantar vein) are connected to each other through the deep venous plantar arch and drain directly into the deep conduct veins (posterior tibial vein, fibula vein, anterior tibial vein) of the lower thigh. The valvelss perforans veins of the sole of the foot connect the deep and superficial veins of the foot with one another and participates, when the foot is under pressure, in the squeezing of the
sponge-like network of the sole of the foot. This vein network of the sole is one of the pressure-suctorial-pumps of the ankle- and gastrocnemius pumps. The supporting of this sole pumps of the foot accelerates the venous reflux in the leg.

The VenoPed shoe insole:

supports the muscle pumps of the foot and accelerates the evacuation in the venous network of the sole through special positionings. This results in a permanent stimulation of this sole region of the foot.

In contrary to surgical stockings, whereby perfusion disturbances are contraindicated, there are no hindrances in the application of the VenoPed insole.

Subjects:

25 women and 25 men were selected (compare tables). Before studies began, a clinical classification of the venous insufficiency was carried out on all subjects in conformity with the CEAP-classification (according to Porter and Moneta). Only subjects who could be categorised under the classification C1 (little varicose veins, no indication of an inherited varicose vein) were taken up for the study. The question of the so-called transfascial ostium insufficiency was initially ruled out through the use of Duplex sontopography. Also before the study began, through the usage of an oscillograph and Doppler sontopography, every subject was checked of an arterial blockage which results in a reduction of the arterial flow. Non of the subjects had been previously treated of diseases regarding their venous system. There existed no accompanying lymphoedemae. In each case, the state of the heart corresponded to the age and had no indication of pathological insufficiency.

There existed no restrictions in the mobility of the upper ankle of the subjects after measurements were taken according to the Neutral-Null-Method.

Method:

The flow velocity of the venous blood in the proximal superficial femoral vein distal to the ostium of the femoral vein profunda was measured with a colour-coded Duplex sontopography.

The wave angle lay between 40 and 60 degrees. The patients were measured while lying in a supine position with the upper part of the body elevated by 25 degrees and the legs placed in a slightly outwards-rotated position. The room temperature measured 20 degrees and there was no adaptation phase needed for the positioning.

Two measuring cycles were carried out. One measuring cycle to determine the flow velocity in the superficial femoral veins in the mornings and ten hours later after a normal daily routine. In the second cycle, a morning measurement was also carried out and a second measurement taken ten hours later after a normal daily routine wearing the VenoPed arch-support.

The subjects had different daily routines, predominantly standing, predominantly sitting as well as standing, sitting and walking normally.

Results:

On the average, after the wearing of the VenoPed shoe insole, there resulted an increase between 35% and 38% in the velocity of the venous reflux. Through this considerable increase of the venous reflux, the peripheral venous pressure is distinctly reduced.

For all vein diseases, which cause extreme restrictions of the haemodynamics, exists a distinct increase of the peripheral venous pressure which directly leads to the feared complex symptoms of the chronic venous insufficiency.

Hence, the VenoPed shoe insole contributes decisively to a timely positive influence of vein complaints particularly in the case of a non-manifested vein complaint.

VenoPed - Clinical study

Women

	Age	Flow velocity cm/s mornings in the quiet period	Flow velocity cm/s evenings after daily stress without VenoPed	Flow velocity cm/s evenings after daily stress with VenoPed
1	31	15	14	18
2	58	14	17	22
3	67	19	18	20
4	57	21	20	28
5	36	18	16	30
6	56	24	26	27
7	34	29	30	35
8	38	22	24	26
9	61	16	19	24
10	33	27	27	36
11	65	21	20	30
12	45	18	17	31
13	23	25	23	31
14	43	19	18	29
15	53	14	13	17
16	37	22	21	27
17	47	13	12	28
18	51	27	26	28
19	55	26	25	32
20	77	17	20	31
21	47	15	17	30
22	47	19	20	27
23	43	23	25	30
24	53	18	18	27
25	55	24	26	32

Average value		48,5	20,24	20,48	27,84
Average height		163,6cm			Increase in flow
Average weight		68,4			velocity by 35%

VenoPed - Clinical study

Men

	Age	Flow velocity cm/s mornings in the quiet period	Flow velocity cm/s evenings after daily stress without VenoPed	Flow velocity cm/s evenings after daily stress with VenoPed
1	53	21	20	29
2	57	24	25	28
3	56	17	17	22
4	48	16	18	30
5	71	19	16	21
6	60	17	16	25
7	40	29	25	37
8	44	31	30	39
9	63	21	22	32
10	60	16	17	26
11	45	16	14	29
12	47	27	25	37
13	22	28	29	37
14	39	30	28	41
15	48	32	31	34
16	38	18	19	24
17	32	27	26	35
18	56	15	17	20
19	61	12	10	22
20	44	16	15	24
21	58	11	13	17
22	58	23	21	30
23	67	18	19	30
24	46	22	23	28
25	25	27	29	33

Average value		49,5	21,32	21	29,2
Average height		169,8cm			Increase in flow
Average weight		76,7			velocity by 39%

ENCLOSURE B

14.WORLD CONGRESS OF THE UNION INTERNATIONALE DE PHLEBOLOGIE

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